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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/853,188

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/853,188	Applicant(s) ABULJADAYEL, ILHAM MOHAMED SALEH SAEED	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 101 and 104-107 is/are allowed.
- 6) ☐ Claim(s) 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32 and 34-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,5,7,11,13,15,17,19,20,22,23,25,26,28-32,34-41,101 and 104-107.

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DETAILED ACTION

Claims 1-3, 28, 30-32, , 34, 35, 37, 39, 40, 41 and 101 have been amended. Claims 12, 18, 21, 24, 27, 33 and 42-100 have been canceled. Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 22, 23, 25, 26, 28-32, 34-41, 101 and 104-107 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 7, 11, , 13, 15, 17, , 19, 20, 22, 23, 25, 26 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are means plus function claims. The specification has provided a drawing of the claimed apparatus. Individual elements of said apparatus, such as a means for introducing into a chamber, incubation means , computer means, means for measuring the volume of a cell population, means for conducting cell counts and mixing means, timing means, CO2 control means, removal means, sealing means and communicating means are known within the art. However, “harvesting means” is claimed separately from “removal means”. A description of "harvesting means" which defines “harvesting” as separate from that of “removal” means has not been provided or defined by the specification, and the art cannot be relied upon to establish the structure of a harvesting means that differs from a removal means because the specification fails to address the metes and bounds of "harvesting" as opposed to "removal”

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 3, 5, 7, 11, , 13, 15, 17, , 19, 20, 22, 23, 25, 26 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3 and 15 specify "harvesting means" as part of the claimed apparatus. The specification contemplates "harvesting means" as separate from "removal means" but fails to provide a structure for a harvesting means which would be different from that of a common removal means. The art cannot be relied upon in this case, because "harvesting" in the context of the intended use of the claimed apparatus implies a type of separation, and the structural means for carrying out a separation has not been described by the instant specification.

Claim 3 recites "transfer means for transferring a column of agent to the chamber" and "Mixing means for mixing the cell population and agent within the chamber". However, these embodiments are required for claim 1 on which claim 3 is dependent. It is unclear how the recitation of the above embodiments as alternative properties of claim 1 further limits the scope of claim 1. Claim 3 recites "wherein the cell population comprises haematopoietic cells", however, this limitation is a requirement of claim 1. It is unclear how the recitation of this embodiment further limits the scope of claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilford (U.S. 4,058,367).

Claims 1, 2, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 are drawn to a device comprising a chamber, means for introducing into said chamber a cell population, means for introducing into said chamber an agent, incubation means and mixing means. Claim 3 embodies the device of claim 1 further comprising means for conducting cell counts; transfer means, temperature

control means, mixing means and removal means. Claim 7 embodies the device of claim 3 wherein the means for conducting cell counts is a cytometer. Claim 17 embodies the device of claim 3 including a microprocessor.

It is noted that means for introducing into said chamber an agent capable of increasing the relative number of undifferentiated cells in a cell population is not given patentable weight because it refers only to the intended use of the agent. Section 2106 of the MPEP states

Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation.

Thus, the intended use of device, wherein the agents are limited to the antibody which binds to MHC antigens, erythropoietin or GM-CSF has not been given patentable weight

It is further noted that noted that the recitation of a device for forming and/or increasing the relative number of undifferentiated cells in a cell population comprising hematopoietic cells has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Gilford et al discloses a device comprising a chamber for blood (abstract, 4th paragraph), means for introducing an agent into said blood, incubation means (column 5, lines 8-10), , mixing means (column 8, lines 67-68) and a microprocessor means (column 5, lines 32-54), as well as a cell counting and sizing apparatus (column 1, lines 67-68) which fulfills the requirement of claim 7 requiring a cytometer. .

Given that the device of the prior art comprises the same structural elements as claimed in the instant device, the claimed device is anticipated because the prior art device will inherently have all the functional characterizes of the claimed device . See *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993).

Claims 1-3, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomioka et al (U.S. 4,983,359).

Tomioka et al disclose a device comprising an incubator, mixing means, a flow cytometer and a data processing means, said data processing means fulfilling the specific requirement of the microprocessor of claim 17 (claims 1 and 2 of '359). Tomioka et al disclose a transfer means for blood cells which is a syringe coupled to a pipette (column 4, lines 4-7). Tomioka et al disclose a transfer means for a monoclonal antibody which is a syringe coupled to a pipette (column 4, lines 24-35).

Given that the device of the prior art comprises the same structural elements as claimed in the instant device, the claimed device is anticipated because the prior art device will inherently have all the functional characterizes of the claimed device . See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 7, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilford (U.S. 4,058,367) in view of what is well known in the art as evidenced by North (2001/0052763).

Claim 5 embodies the device of claim 3 wherein the means for conducting cell counts is a coulter counter.

Gilford et al teaches said device with a cell counter, but does not specifically disclose a Coulter Counter.

Use of a Coulter Counter as a specific cell counter is well known in the art as exemplified by North, who teaches that the Coulter counter is particle counter useful for blood cell counting and invented in 1953 (paragraph [003]).

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It would have been prima facie obvious at the time the claimed invention was made to use a Coulter Counter as a cell counter as part of the device of Gilford. One of skill in the art would have been motivated to do so because the Coulter Counter is well known as a means for counting blood cells as exemplified by North.

Claims 1-3, 7, 11, 13, 17, 19, 20, 22, 23, 25, 26, 28, 29-32, 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomioka et al (U.S. 4,983,359) in view of Johnson et al (U.S. 4,563,907).

Claims 11 and 13 embody the device of claim 3 wherein the transfer means is a syringe driven by a motor.

Tomioka et al teaches a syringe which operates a pipette as a transfer means. Tomioka et al do not specifically state that said syringe is a motor driven syringe.

Johnson et al teach a motor driven syringe for controlling a pipette (column 4, first paragraph). Johnson et al teach that the improvement associated with the use thereof being the elimination of operator interaction for the specification of the quantity of material to be transferred (abstract).

It would have been prima facie obvious at the time the claimed invention was made to use a motor driven syringe in the device of Tomioka et al. One of skill in the art would have been motivated to do so by the teachings of Johnson et al on the improvement associated with the use thereof being the elimination of operator interaction for the specification of the quantity of material to be transferred (abstract).

Claims 101 and 104-107 are free of the art.

All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicant's amendments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643